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EXAMINER

BEISNER, WILLIAM H

ART UNIT

PAPER NUMBER

1744

DATE MAILED: 12/01/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/916,419

Applicant(s)

KELLEHER ET AL.

Examiner

William H. Beisner

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 13 September 2005.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-21 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-21 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Claim Rejections - 35 USC § 112

1. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

2. Claims 1-21 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

Instant claims 1-21 recite the following claim limitations: i) “a film formed of a plurality of molecules; ii) a sample fluid having a plurality of microorganisms; and/or iii) the microorganisms interact with at least one of the molecules in response to excitation light so as to generate or create a fluorescent signal. With respect to item i) above, review of the originally filed specification fails to provide guidance as to any specific substances which have the ability to generate a signal in response to interacting with a “microorganism” that has been excited to interact with the film of molecules. The specification does recite that the molecules can be “conjugated polymer molecules” but again fails to set forth specific molecules that would be capable of functioning as recited in the claim and/or that would be known to one of ordinary skill in the art at the time of filing the instant invention. With respect to item ii) above, review of the originally filed specification indicates that the claim language “microorganism” encompasses a wide range of potential analytes including biological and chemical agents, such as TNT. This

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would convey to one of ordinary skill in the art that all of the possible “microorganism” listed in the specification could be used and would function in the instantly claimed device. With respect to item iii) above, while the originally filed specification includes numerous references to the fact that the “microorganisms” interact with the film of molecules in response to excitation light wherein the interaction generates a fluorescent signal (See pages 5, 11 and 12 of the instant specification) and the specification lists a number of possible “microorganisms”, the specification fails to provide guidance as to any specific combination of “microorganism”, excitation light and film molecule that would provide the signal generation of fluorescent light required of the instant claims. Note when discussing the state of the prior art, the instant specification (See pages 1-2) states that the excitation light “induces any fluorescence emitting agent present in the sample to fluoresce”. The discussion of the prior art is silent as to any agent, entity and/or microorganism that “interacts” with a film of molecules in response to an excitation light. Also the prior art of the references of Grey et al.(US 5,157,261) and Ligler et al.(US 5,496,700) are both drawn to fluorescence detection systems for the detection of “microorganisms”. The reference of Grey et al. is drawn to the detection of TNT while the reference of Ligler et al. is drawn to the detection of microbiological agents. Neither of these references convey to one of ordinary skill in the art that either of the detected analytes “interact” with a film of molecules “in response to an excitation light”. No working examples are provided to provide such missing information. Without such information, one skilled in the art could not predict which “microorganisms” from the vast number of possible microorganisms would respond to an excitation light to interact with a film of molecules as required of the instant claims. Furthermore, one skilled in the art would not be capable of determining which “polymer

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molecules” and/or “conjugated polymer molecules” could be used that would interact with a microorganism to generate a fluorescent signal. In view of this lack of information, one skill in the art would be required to perform undue experimentation to identify any “microorganisms” and/or “polymer molecules” that would be responsive to excitation light and interact to generate or created a fluorescence signal as required of the instant claims. Therefore, one skilled in the art could not make the invention without undue experimentation.

3. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

4. Claims 1-21 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 1-21 are indefinite for the following reason. It is not clear what is responsive to the recited excitation light. Does the excitation light cause the microorganisms to “interact” with the film molecules or is the excitation light merely being used to generate a fluorescence emission from fluorescence emitting entities within the detection device. Does this “interaction” differ from the prior art discussed on pages 1, 2 and 7 of the instant specification? Clarification and/or correction is requested.

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5. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

6. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

7. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

8. Claims 1, 3-9 and 11-20 are rejected under 35 U.S.C. 103(a) as being unpatentable over Grey et al.(US 5,157,261) in view of Broeng et al.(WO 99/64903).

The reference of Grey et al. discloses a fluorescence detection system which includes a fiber optic (18) which includes a surface coated with a plurality of molecules (See all of column

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3). A sample fluid having a plurality of microorganisms (TNT) (See applicants' definition of microorganism on page 12, lines 16-23, of the instant specification) dispersed therein is contacted with the coated molecules. The device includes an optical source for generating excitation light and an optical detector for detecting a resultant fluorescence signal (See column 6, line 60, to column 7, line 2). Note while the interaction of the TNT and PAH results in a decrease, quenching or reduction of an already existing activity, a fluorescent signal is generated in response to the excitation light since no fluorescent signal exists in the absence of an excitation light.

The above claims differ by reciting the use of a photonic band gap structure with an internal core region for supporting the coated molecules wherein the sample fluid is contacted or contained within the core region.

The reference of Broeng et al. discloses that it is known in the art to employ photonic band gap optical fibers in sensor applications because of the advantages associated with these structures over conventional fiber optical waveguides (See pages 1-7). The reference discloses providing a void in the fiber and means for providing a sample gas or liquid in the void (See pages 19-20).

In view of this teaching, it would have been obvious to one of ordinary skill in the art at the time the invention was made to employ a photonic band gap structure in place of the conventional cladded optical fiber of the primary reference for the known and expected advantages associated with the photonic band gap structure as discussed by the reference of Broeng et al.

With respect to claims 3, 14 and 15, the reference of Grey et al. discloses the use of a

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conjugated polymer structure for interacting with the microorganism (TNT). Note, the interaction of the TNT molecules with the PAH coating is considered to meet these claim limitations.

With respect to the claimed wavelengths and/or dimensions of claims 4, 5, 7, 8, 12, 13, 18 and 20, it would have been obvious to one of ordinary skill in the art to determine the optimum construction of the device based merely on the microorganism and molecule employed while maintaining the efficiency of the detection system.

With respect to claim 6, the coating material includes a fluorescing agent, PAH.

With respect to claims 9 and 11, while the references of Grey et al. and Broeng et al. disclose the use of excitation light and light detection, the references are silent as to specific light source and detector. However, it would have been obvious to one of ordinary skill in the art to determine which light source to employ and detector based merely on the specifics of the detection to be performed. Note both lasers and photomultiplier tubes are notoriously well known in the art of chemical optical detection.

With respect to claims 16 and 17, the device is capable of being used with either a gas or liquid sample (See page 20 of Broeng et al.).

With respect to claim 19, the structure of Broeng et al. is considered a photonic band gap fiber.

9. Claims 1-5, 7-13 and 16-20 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ligler et al.(US 5,496,700) in view of Broeng et al.(WO 99/64903).

The reference of Ligler et al. discloses a fluorescence detection system that can be which

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includes a fiber optic (10) which includes a surface coated with a plurality of molecules (See Figure 2). A sample fluid having a plurality of microorganisms (30) dispersed therein is contacted with the coated molecules. The device includes an optical source for generating excitation light and an optical detector for detecting a resultant fluorescence signal (See Figure 2 and Example 2). Note that the interaction of the dyed sample of microorganisms with the capture molecule on the surface of the fiber optic waveguide meets the limitations of claim 1 since when the bound microorganism is excited with light, a fluorescent signal is generated that is detected by the detection device.

The above claims differ by reciting the use of a photonic band gap structure with an internal core region for supporting the coated molecules wherein the sample fluid is contacted or contained within the core region.

The reference of Broeng et al. discloses that it is known in the art to employ photonic band gap optical fibers in sensor applications because of the advantages associated with these structures over conventional fiber optical waveguides (See pages 1-7). The reference discloses providing a void in the fiber and means for providing a sample gas or liquid in the void (See pages 19-20).

In view of this teaching, it would have been obvious to one of ordinary skill in the art at the time the invention was made to employ a photonic band gap structure in place of the conventional cladded optical fiber of the primary reference for the known and expected advantages associated with the photonic band gap structure as discussed by the reference of Broeng et al.

With respect to claim 2, the microorganisms bind with the molecules on the surface.

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With respect to claim 3, the binding molecules are conjugated onto the surface of the optical structure (See Example 2).

With respect to the claimed wavelengths and/or dimensions of claims 4, 5, 7, 8, 12, 13, 18 and 20, it would have been obvious to one of ordinary skill in the art to determine the optimum construction of the device based merely on the microorganism and molecule employed while maintaining the efficiency of the detection system.

With respect to claim 9, the reference of Ligler et al. discloses the use of a laser (See Example 2).

With respect to claim 10, the detected microorganisms are bacteria (See Example 2).

With respect to claim 11, while the reference of Ligler et al. discloses the use of a photodiode, it would have been obvious to one of ordinary skill in the art to employ alternative detectors based merely on the specifics of the detection to be performed. Note photomultiplier tubes are notoriously well known in the art of chemical optical detection.

With respect to claims 16 and 17, the device is capable of being used with either a gas or liquid sample (See page 20 of Broeng et al.).

With respect to claim 19, the structure of Broeng et al. is considered a photonic band gap fiber.

10. Claim 21 is rejected under 35 U.S.C. 103(a) as being unpatentable over Grey et al.(US 5,157,261) in view of Broeng et al.(WO 99/64903) taken further in view of either Walt et al.(US 5,250,264) or Pinkel et al.(US 5,690,894).

The combination of the references of Grey et al. and Broeng et al. has been discussed

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above.

Claim 21 differs by reciting that the detection system is manufactured as an array of fibers.

Both the references of Walt et al. and Pinkel et al. disclose that it is well known in the art to provide an array of optical fiber structures when performing a chemical detection so as to perform multiple assays (See the abstracts of both references).

In view of either of these teachings, it would have been obvious to one of ordinary skill in the art to employ an array of band gap fibers when employing the device to detect more than one kind of analyte. Each void would include a different molecule and would allow a single sample to be analyzed for a plurality of different analytes.

11. Claim 21 is rejected under 35 U.S.C. 103(a) as being unpatentable over Ligler et al.(US 5,496,700) in view of Broeng et al.(WO 99/64903) taken further in view of either Walt et al.(US 5,250,264) or Pinkel et al.(US 5,690,894).

The combination of the references of Ligler et al. and Broeng et al. has been discussed above.

Claim 21 differs by reciting that the detection system is manufactured as an array of fibers.

Both the references of Walt et al. and Pinkel et al. disclose that it is well known in the art to provide an array of optical fiber structures when performing a chemical detection so as to perform multiple assays (See the abstracts of both references).

In view of either of these teachings, it would have been obvious to one of ordinary skill in

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the art to employ an array of band gap fibers when employing the device to detect more than one kind of analyte. Each void would include a different molecule and would allow a single sample to be analyzed for a plurality of different analytes.

Response to Arguments

12. With respect to the rejection of claims 1-21 under 35 USC 112, first paragraph, Applicants advance the following arguments (See pages 6-10 of the response filed 9/13/05) :

i) Conjugated polymer molecules are widely known in the art and can be found in textbooks. As a result, the specification does not need to describe the properties of these molecules in order to meet 35 USC 112, first paragraph.

ii) With respect to “a sample fluid having a plurality of microorganisms”, Applicants argue that the specification clearly defines what limitations are encompassed by the language “microorganisms”.

iii) With respect to “the microorganisms interact with at least one of the molecules in response to excitation light so as to generate or create a fluorescent signal”, Applicants argue that the specification provides ample guidance to how a fluorescent signal is generated and further state that this type of binding event is “very widely known, and certainly by one of ordinary skill in the art”. Applicants stress that neither the references of Grey et al. or Ligler involve this type of binding event.

In response to argument i) above, while conjugated polymers may be well known in the art, Applicants’ specification fails to even provide any examples of molecules that would

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function in the manner as required of the instant specification and claims. Does this mean that any conjugated molecule would be capable of being used and/or that one of ordinary skill in the art would be capable of determining which molecules would work without undue experimentation? Further more, while applicants assert that these molecules are well known, they have not provided any evidence that these molecules are well known and furthermore have not provided any evidence that conveys to one of ordinary skill in the art that “microorganisms” when excited by light would interact and/or bind with the molecules to generate fluorescent light.

In response to argument ii) above, again while the specification may convey to one of ordinary skill in the art what is encompassed by the term “microorganism”, the Examiner is of the position that the specification fails to convey to one of ordinary skill in the art on how to make and use the invention without undue experimentation. The Examiner submits that one of ordinary skill in the art even when given the list of possible microorganisms would not be capable of making and/or using the instant invention without undue experimentation. Applicants appear to take the position that any conjugated molecules can be used with any of the listed microorganisms. When detecting TNT, applicants’ specification does not even provide guidance as to what conjugated molecules can be used to detect this specific analyte. The Examiner maintains that undue experimentation would be required by one of ordinary skill in the art, especially when Applicants take the position that the disclosure of the Grey et al. reference is different in terms of the fluorescing reaction when detecting for the presence of TNT.

In response to argument iii) above, the fact that the specification includes references to the specific claim language is not persuasive in the absence of specific examples as to what microorganisms and molecules that can function in this manner. In the absence of this guidance,

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the Examiner is of the position that undue experimentation would be required of one having ordinary skill in the art. Applicants' statement that this fluorescing reaction is conventional in the art is not persuasive in the absence of evidence to support this statement. Finally, the references of Grey and Ligler were cited to establish that which is conventional in the art. Namely, the use of molecules that can bind with a desired analyte wherein excitation light is employed to excite any fluorescence emitting agent present in the binding reaction to fluoresce thus indicating the presence of the analyte in the sample to be tested.

13. With respect to the rejection of claims 1-21 under 35 USC 112, second paragraph, Applicants argue (See pages 11-12 of the response filed 9/13/05) that "Anyone with even a rudimentary knowledge of the mechanism of fluorescence generation and detection understands that the microorganisms are the ones that responds to excitation light, by binding to the conjugated polymers, something which is part of the standard knowledge for one of ordinary skill in the art".

In response, the Examiner disagrees. One of ordinary skill in the art recognizes that microorganisms are capable of specifically binding with molecules for detection of the presence of the microorganisms in a sample and that when a fluorescent agent is present in the sample and/or binding reagent, fluorescence is produced in response to emitted light. The Examiner maintains that it is not conventional or readily apparent to one of ordinary skill in the art that microorganisms response to excitation light by binding to conjugated polymers. Applicants have not providing any evidence that this type of reaction is well known or convention to one having ordinary skill in the art.

14. With respect to the rejection of claims 1, 3-9 and 11-20 under 35 USC 103 over the combination of the references of Grey and Broeng, Applicants argue (See pages 12-15 of the response filed 9/13/05) that the rejection is improper for the following reasons:

i) Since the Examiner has stated in the 35 USC 112, first paragraph, rejection that the reference of Grey does not convey to one of ordinary skill in the art the claim limitation that detected analytes interact with a film of molecules in response to an excitation light.

ii) The rejection of record fails to establish the requisite motivation for combining the references of Grey and Broeng.

In response to argument i) above, the Examiner is of the position that the reference of Grey meets the instant claim limitations when combined with the reference of Broeng because of the indefiniteness with respect to the binding event discussed in the instant specification and claims. The Examiner is of the position that the specifics of the invention have been mischaracterized in the specification and claims since the disclosure of Grey is drawn to the detection of TNT with a conjugated polymer film using emitted light and detected fluorescent light resulting from the binding of the TNT microorganism with the polymer film.

In response to argument ii) above, the examiner recognizes that obviousness can only be established by combining or modifying the teachings of the prior art to produce the claimed invention where there is some teaching, suggestion, or motivation to do so found either in the references themselves or in the knowledge generally available to one of ordinary skill in the art. See *In re Fine*, 837 F.2d 1071, 5 USPQ2d 1596 (Fed. Cir. 1988) and *In re Jones*, 958 F.2d 347, 21 USPQ2d 1941 (Fed. Cir. 1992). In this case, the Examiner is of the position that the

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disclosure of the reference of Broeng et al. would have suggested to one of ordinary skill in the art that the substitution of a photonic band gap waveguide for an optical fiber waveguide would have been obvious for the advantages associated with the use of a photonic band gap waveguide. See page 3, lines 23-38, and page 5, lines 18-24, of Broeng et al. which suggest the use of band gap fibers (hollow core fibers) in sensor systems. In response to the comments that the reference of Grey does not disclose i) any cladding or core; ii) an optical fiber core having a higher index of refraction compared to the cladding; and iii) slightest hint in Grey that optical fiber cores having a lower index of refraction compared to the cladding would be advantageous, the Examiner maintains that the combination is proper for the following reasons: i) the fiber optic disclosed by the reference of Grey inherently includes a core and cladding. If not, the fiber optic would not be capable of total internal reflection required to function as is intended in the reference. ii) The fiber optic disclosed by Grey inherently includes a core of a higher index of refraction than the cladding. This is the type of fiber optic discussed and identified by the reference of Broeng et al. as a "high-index core" or "index-guiding" fiber (See page 3, lines 16-21). iii) The reference of Grey was not relied upon to disclose that "low-index core" fibers would be advantageous. The reference of Broeng et al. provides the motivation that a "low-index core" fiber is advantageous over a "high-index core" (See pages 1-7 of Broeng et al.).

15. With respect to the rejection of claims 1-5, 7-13 and 16-20 under 35 USC 103 over the combination of the references of Ligler and Broeng, Applicants argue (See pages 16-19 of the response filed 9/13/05) that the rejection is improper for the following reasons:

i) Since the Examiner has stated in the 35 USC 112, first paragraph, rejection that the reference of Ligler does not convey to one of ordinary skill in the art the claim limitation that detected analytes interact with a film of molecules in response to an excitation light.

ii) The rejection of record fails to establish the requisite motivation for combining the references of Ligler and Broeng.

In response to argument i) above, the Examiner is of the position that the reference of Ligler meets the instant claim limitations when combined with the reference of Broeng because of the indefiniteness with respect to the binding event discussed in the instant specification and claims. The Examiner is of the position that the specifics of the invention have been mischaracterized in the specification and claims since the disclosure of Ligler is drawn to the detection of microorganisms with a conjugated polymer film using emitted light and detected fluorescent light resulting from the binding of the microorganisms with the polymer film.

In response to argument ii) above, the examiner recognizes that obviousness can only be established by combining or modifying the teachings of the prior art to produce the claimed invention where there is some teaching, suggestion, or motivation to do so found either in the references themselves or in the knowledge generally available to one of ordinary skill in the art. See *In re Fine*, 837 F.2d 1071, 5 USPQ2d 1596 (Fed. Cir. 1988) and *In re Jones*, 958 F.2d 347, 21 USPQ2d 1941 (Fed. Cir. 1992). In this case, the Examiner is of the position that the disclosure of the reference of Broeng et al. would have suggested to one of ordinary skill in the art that the substitution of a photonic band gap waveguide for an optical fiber waveguide would have been obvious for the advantages associated with the use of a photonic band gap waveguide. See page 3, lines 23-38, and page 5, lines 18-24, of Broeng et al. which suggest the use of band

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gap fibers (hollow core fibers) in sensor systems. In response to the comments that the reference of Ligler et al. does not disclose i) any cladding or core; ii) an optical fiber core having a higher index of refraction compared to the cladding; and iii) slightest hint in Ligler et al. that optical fiber cores having a lower index of refraction compared to the cladding would be advantageous, the Examiner maintains that the combination is proper for the following reasons: i) the fiber optic disclosed by the reference of Ligler et al. inherently includes a core and cladding. If not, the fiber optic would not be capable of total internal reflection required to function as is intended in the reference. ii) The fiber optic disclosed by Ligler et al. inherently includes a core of a higher index of refraction than the cladding. This is the type of fiber optic discussed and identified by the reference of Broeng et al. as a "high-index core" or "index-guiding" fiber (See page 3, lines 16-21). iii) The reference of Ligler et al. was not relied upon to disclose that "low-index core" fibers would be advantageous. The reference of Broeng et al. provides the motivation that a "low-index core" fiber is advantageous over a "high-index core" (See pages 1-7 of Broeng et al.). Additionally the Examiner is of the position that the interaction of the dyed sample with microorganisms with the capture molecule on the surface of the fiber optic waveguide meets the limitations of element 3) in instant claim 1 since when the bound microorganism is excited with light a fluorescent signal is generated that is detected by the detection device. Also, the instant specification indicates that microorganisms such as those disclosed by the reference of Ligler et al. are detected upon binding or interacting with the surface molecules. Since the instant specification discloses detection of the same microorganisms and is silent as to the specific binding or interaction molecule employed, the Examiner is of the position that the reaction disclosed by the reference of Ligler et al. is the same as that required of the instant claims. The

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only difference is that Ligler et al. employs a fiber optical waveguide while the instant claims require a photonic band gap waveguide. The reference of Broeng addresses the obviousness of the substitution of a photonic band gap waveguide for an optical fiber waveguide.

16. With respect to the rejection of claim 21 under 35 USC 103 over the combination of the references of Grey et al., Broeng et al., and either Walt et al. or Pinkel et al., Applicants advance the following arguments:

i) None of the references alone discloses, suggests or teaches the claimed structure of claim 21.

ii) The combination of the references is improper “because nowhere in the cited references is there any suggestion, teaching, or motivation to combine the references on which the rejection is based”.

iii) Even if the references are properly combined, the limitations of claim 21 have not been met.

In response to argument i) above, the combination of the references addresses these claim limitations. Note one cannot show nonobviousness by attacking references individually where the rejections are based on combinations of references. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981); *In re Merck & Co.*, 800 F.2d 1091, 231 USPQ 375 (Fed. Cir. 1986).

In response to argument ii) above, the examiner recognizes that obviousness can only be established by combining or modifying the teachings of the prior art to produce the claimed invention where there is some teaching, suggestion, or motivation to do so found either in the references themselves or in the knowledge generally available to one of ordinary skill in the art.

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See *In re Fine*, 837 F.2d 1071, 5 USPQ2d 1596 (Fed. Cir. 1988) and *In re Jones*, 958 F.2d 347, 21 USPQ2d 1941 (Fed. Cir. 1992). In this case, the Examiner is of the position that the disclosure of the reference of Broeng et al. would have suggested to one of ordinary skill in the art that the substitution of a photonic band gap waveguide for an optical fiber waveguide would have been obvious for the advantages associated with the use of a photonic band gap waveguide. See page 3, lines 23-38, and page 5, lines 18-24, of Broeng et al. which suggest the use of band gap fibers (hollow core fibers) in sensor systems. The references of Walt et al. and Pinkel et al. were cited merely as tertiary references that disclose to one of ordinary skill in the art that the use of arrays of optical sensing devices is conventional in the art.

In response to argument iii) above, the Examiner is of the position that the combination of the references meet the claim limitations of claim 1 for the same reasons as set forth with respect to arguments i) and ii) above.

17. With respect to the rejection of claim 21 under 35 USC 103 over the combination of the references of Ligler et al., Broeng et al., and either Walt et al. or Pinkel et al., Applicants advance the following arguments:

i) None of the references alone discloses, suggests or teaches the claimed structure of claim 21.

ii) The combination of the references is improper “because nowhere in the cited references is there any suggestion, teaching, or motivation to combine the references on which the rejection is based”.

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iii) Even if the references are properly combined, the limitations of claim 21 have not been met.

In response to argument i) above, the combination of the references addresses these claim limitations. Note one cannot show nonobviousness by attacking references individually where the rejections are based on combinations of references. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981); *In re Merck & Co.*, 800 F.2d 1091, 231 USPQ 375 (Fed. Cir. 1986).

In response to argument ii) above, the examiner recognizes that obviousness can only be established by combining or modifying the teachings of the prior art to produce the claimed invention where there is some teaching, suggestion, or motivation to do so found either in the references themselves or in the knowledge generally available to one of ordinary skill in the art. See *In re Fine*, 837 F.2d 1071, 5 USPQ2d 1596 (Fed. Cir. 1988) and *In re Jones*, 958 F.2d 347, 21 USPQ2d 1941 (Fed. Cir. 1992). In this case, the Examiner is of the position that the disclosure of the reference of Broeng et al. would have suggested to one of ordinary skill in the art that the substitution of a photonic band gap waveguide for an optical fiber waveguide would have been obvious for the advantages associated with the use of a photonic band gap waveguide. See page 3, lines 23-38, and page 5, lines 18-24, of Broeng et al. which suggest the use of band gap fibers (hollow core fibers) in sensor systems. The references of Walt et al. and Pinkel et al. were cited merely as tertiary references that disclose to one of ordinary skill in the art that the use of arrays of optical sensing devices is conventional in the art.

In response to argument iii) above, the Examiner is of the position that the combination of the references meet the claim limitations of claim 1 for the same reasons as set forth with respect to arguments i) and ii) above.

Conclusion

18. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

19. Any inquiry concerning this communication or earlier communications from the examiner should be directed to William H. Beisner whose telephone number is 571-272-1269. The examiner can normally be reached on Tues. to Fri. and alt. Mon. from 6:15am to 3:45pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Richard Crispino can be reached on 571-272-1226. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



William H. Beisner
Primary Examiner
Art Unit 1744

WHB